**REPLY DECLARATION OF CHRISTOPHER J. MCDONALD IN FURTHER SUPPORT OF END-PAYOR PLAINTIFFS' MOTION FOR CLASS CERTIFICATION [PUBLIC VERSION]**

# Exhibit 65

# Part 3 of 3

information-rich environment—and one that will present some interesting challenges not only to pharmaceutical manufacturers but also to health economists and health care purchasers. Unless a more eclectic regulatory position is taken, it is most unlikely that the discipline of pharmacoeconomics will become anything more than an exercise in generating clinical trial-based cost-outcomes ratios.

### Impact of Drug Formularies on Drug Access and Utilization

Overly restrictive formularies may deny patients access to necessary medications. This assertion has prompted criticism of restrictive or closed drug formularies. However, managed care counters that in developing their formularies all necessary drugs are included and, by definition, if a drug is not included in the formulary, it is not necessary and there is an alternate and equally effective product on the formulary. Walser, Ross-Degnan, and Soumerai concluded that the elimination of restrictive Medicaid formularies improved access to 200 of the most prescribed drugs, but most of these popular drugs added no therapeutic benefit.[57] In general, restrictive Medicaid formularies have prevented access to new drug introductions.[58] Very little is known about the ultimate impact on patient outcomes as a result of pharmacy benefit programs.[59,60] Not exclusively a U.S. phenomenon, the European economic community has also found that the rational development of a drug formulary can have positive financial benefits without jeopardizing patient care.[61] Gross found no evidence that the use of formularies adversely affects patients' access to pharmaceutical care.[62]

Drug formularies will continue to be used and will generally grow more restrictive with greater use of NDC blocks, eliminating coverage of certain drug products.[63,64] However, this is not consistent across all health plans, as indicated previously. Many plans will use a combination of NDC blocks and higher and tiered copayments to limit access and influence use of formulary products. Pharmaceutical manufacturers must continue their organization-specific intelligence gathering so that they understand the current and future access and utilization control strategies of their key managed care customers.

Prior authorization (PA) of selected drugs is another formulary control activity that is commonly used to control access and use of expensive products or those drugs that have a high abuse or misuse potential. PA programs are expensive, unfriendly to patients, and administratively cumbersome, and they often cost $5.00 to $15.00 per PA episode. Therefore, we are also seeing PBMs and HMOs use higher and tiered copayments for products normally subject to a PA to eliminate the frustration involved with a physician or pharmacist trying to obtain authorization to prescribe or dispense a drug.

The result of these formulary changes is to shift the financial burden and demand management function to the patient by way of a utilization copayment. This also reduces the objectionable use of noncoverage activities (i.e., NDC blocks or prior authorization). Essentially, patients can have whatever they want, as long as they accept the financial responsibility associated with their decision.

### Mandatory Generic Substitution Program

Mandatory dispensing of generic drugs is perhaps the single most effective cost-containment drug formulary component available. Aggressively promoting the use of generic drugs when appropriate can reduce pharmacy program costs by approximately 10 to 15 percent. The National Association of Chain Drug Stores reported that the average price of brand prescriptions was $53.51 in 1998, whereas the average generic prescription price was $17.33, approximately one third the price of branded prescriptions. An MCO with an aggressive generic substitution program can have at least 50 percent of prescriptions dispensed generically without compromising patient care.

To take advantage of the lower acquisition price of generic drugs, the pharmacy program administrator will set the amount of reimbursement for

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each generic drug product. This may be called the "maximum allowable cost" or MAC. If an MCO or PBM establishes a MAC on a drug product, this means that the pharmacist will only be reimbursed at the MAC, regardless if a generic is dispensed or if the pharmacist dispenses a more expensive brand product. If an MCO or PBM has a "MAC program" and if a pharmacist dispenses a more expensive brand product, the pharmacist will not receive complete reimbursement. In this situation, the patient will be asked to pay the difference between the brand name drug cost and the generic MAC-level of reimbursement.

Managed care generally supports the use of generic drugs and anxiously awaits the patent expiration of expensive brand medications that are highly used. In 1999, IMS America estimated that approximately $1.2 billion of generic savings could result in the United States from the brand products that will be available as generic drugs for the first time. This number is expected to increase to $5.2 billion in 2000, drop down to $3.7 billion in 2001, and rise to $7.5 billion in 2002.

### Role of the Drug Formulary and Treatment Guidelines

Many health plans and PBMs use treatment guidelines or algorithms to minimize treatment variations and to improve outcomes for patients while reducing costs. The purpose of guidelines is to promote the appropriate use of the most cost-effective pharmaceuticals. Guidelines are often derived from medical specialty societies or governmental entities, such as the National Institutes of Health or the Agency for Health Care Policy and Research (AHCPR). Also called clinical pathways or treatment protocols, clinical guidelines are recommendations to practitioners of a course of action concerning diagnosis and treatment of a specific disease or medical condition. Often drug formulary documents include treatment guidelines within appropriate therapeutic category sections. Clinical guidelines are discussed in detail in Chapter 29 of *The Managed Health Care Handbook, Fourth Edition.*

### PHARMACEUTICAL MANUFACTURER DISCOUNT AND REBATE CONTRACTS

Health plans and PBMs that can effectively enforce drug formularies and influence physician prescribing and pharmacy dispensing may negotiate discount contracts with pharmaceutical manufacturers. The contracts are often performance based and provide financial rewards to the health plan or PBM if the market share or volume of the products under contract increases. Contracts may provide off-invoice discounts on purchased drugs (for in-house pharmacies that take possession of drugs) or rebates on used drugs (for community-based pharmacy networks). The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) places effective limitations on the level of rebate, usually to approximately 15 percent. Manufacturers must provide equivalent rebates to Medicaid pharmacy programs. Health plans and PBMs may pass on some of the discounts to their payer-customers or to provider physicians or pharmacists as incentives for prescribing and dispensing formulary drugs. Table 15–4 illustrates the potential cost impact of a rebate. As shown, generic drug "A" offers the payer a much lower net cost ($6.50) but offers no rebate income. Brand drug "B" subject to a rebate contract offers a net cost of $15.00 to the payer and a $1.50 rebate income to the PBM (or health plan) that holds the contract with the manufacturer. Brand drug "C" is priced the same as drug "B," but drug "C" does not have a rebate associated with it. As a result, drug "C" is more expensive to the payer ($18.00) and offers the PBM or HMO no rebate income. If drugs "B" and "C" are equivalent, the presence of the rebate would influence the P & T committee to select drug "B" if a brand name drug is preferred. If a generic product is acceptable, drugs "A," "B," and "C" would be subject to a MAC and would all be reimbursed at the same level. As a result, pharmacies would dispense drug "A" only, unless the patient was willing to pay the cost difference between the MAC level of reimbursement and the cost of drugs "B" or "C."

Table 15–4 Illustration of the Cost Impact of the Rebate

| | *Generic A* | *Brand B* | *Brand C* |
|---|---|---|---|
| Drug AWP* | $10.00 | $30.00 | $30.00 |
| Drug AWP—15%** | $ 8.50 | $25.50 | $25.50 |
| Dispensing Fee*** | $ 3.00 | $ 2.50 | $ 2.50 |
| Prescription Subtotal | $11.50 | $28.00 | $28.00 |
| Tiered Copay | $ 5.00 | $10.00 | $10.00 |
| Net Subtotal Cost | $ 6.50 | $18.00 | $18.00 |
| 10% Rebate (Drug B) | — | $ 3.00 | — |
| Net Total Cost | $ 6.50 | $15.00 | $18.00 |
| 50% Rebate Share | — | $ 1.50 | — |
| Net Cost to Payer | $ 6.50 | $16.50 | $18.00 |
| Rebate Income to PBM | — | $ 1.50 | — |

*Source:* Robert P. Navarro, 2000.
*AWP = average wholesale price.
**15% is typical discount on published drug ingredient cost (AWP).
***Pharmacist received additional $0.50 fee for dispensing a generic.

## PRESCRIPTION PATIENT COPAYMENTS

Managed care members are usually required by contract to pay a copayment for each prescription they obtain for three reasons. First, the copayment is a method that involves the patient as a financial risk-sharing partner in the quest to control the cost of the prescription drug program. Second, the copayment should influence the patient's behavior to select a lower copayment drug that has a lower cost to the HMO or PBM. Third, a copayment introduces a hesitation factor designed to discourage unnecessary or trivial use of prescription drugs. Traditionally, health plans attempted to set the prescription copayment at approximately 25 percent of the average prescription cost and adjust the copayment annually as the prescription costs increased. Therefore, if the average brand prescription cost is $45.00, the average brand copayment would be $11.25. This general guideline usually holds true, although other competitive factors and rebate contracts may influence in what formulary copayment tiers drug products will be placed. Certain union trusts or state Medicaid programs may choose not to require a copayment or have a very low copayment (e.g., $1.00 per prescription). Copayment must be high enough to achieve the desired financial goals but not too high as to discourage or prevent the appropriate use of cost-effective pharmaceuticals.

Employer groups and managed care have been frustrated by their apparent inability to contain rising pharmacy program costs and now have gone to the ultimate user of health care products and services, the member-patients, in an attempt to control costs and use of pharmaceuticals. Employers and managed care have routinely levied higher and tiered user fees (copayments) on most health care products and services used. Some health benefit programs, such as many Medicare programs or indemnity-style insurance, also have front-end deductibles, benefit maximums, or both as cost-containment features to help limit the financial exposure of the health plan. We will likely see a greater array of benefit designs with different levels of front-end deductibles, copayment tiers, and benefit caps from which members can select on the basis of their health care demands, financial status, and willingness to pay. As this occurs, individual patients will be even more appropriate targets for a direct-to-consumer marketing message.

Economic theory suggests that the demand for prescriptions should fall as the price increases,

| *Brand C* |
|---|
| $30.00 |
| $25.50 |
| $ 2.50 |
| $28.00 |
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all else being equal. This assertion is based on Grossman's derived demand model, which contends that the demand for medical care and prescription drugs flows from an underlying demand for health.[65] Other studies have shown a slight or modest reduction in drug use with higher copayments.[66–68] However, there is not universal consistency in the limited number of copayment studies. The demand elasticity is highly variable and depends on a patient's financial abilities, perception of heath needs, perception of the value of the desired resource, the influence of the patient's physician and other external influencers.

### Copayment Tiers

Copayments are increasing in dollar amount and becoming increasingly tiered to share costs and influence patient demand. However, despite continuously rising AWP ingredient cost, according to a national survey of 333 employer plan sponsors, retail prescription copays for brand medications rose only 6.6 percent between 1995 and 1997.[69] An unpublished study of 20 MCOs (5 PBMs with an average membership of 20 million lives) and 15 HMOs (average membership of 1.1 million lives) revealed the copayment tier levels shown in Table 15–5.

Not all copayment schemes are effective in shifting costs and influencing patient demand. Consider the example in Table 15–6 in which the copayment results in the member selecting a drug in the next lower copayment (e.g., paying the Tier III nonpreferred brand copayment versus influencing the member to switch to the Tier II preferred brand).

If health plans only shift cost without influencing drug use behavior, they will reduce some costs by shifting some of the drug costs to the patient through copayments but will not experience the full potential of changing patient behavior. As indicated previously, it is preferable to influence the patient to accept a lower tiered product for additional savings. This is particularly important for chronic medications because with each month of use, the plan will save an additional $10 if a Tier II product is used in place of a Tier III product in this example.

Pharmacy directors generally believe that an inter-tier change of at least $10.00 is necessary to influence patient decisions. However, this is highly dependent on patients' socioeconomic levels. There may limited elasticity in the demand of pharmaceuticals from the patients' perspective.

### Physician Response to Rising Copayments

Physicians are generally unaware of the copayment level of the products they prescribe because they pay little attention to the multiple printed formularies of the numerous health plans with which they participate. It is generally only

Table 15–5 Copayment Tiers

| *MCO Type* | *Average Tier I Generic Copayment (Range)* | *Average Tier II Formulary or Preferred Brand Copayment (Range)* | *Average Tier III Nonformulary or Nonpreferred Brand Copayment (Range)* |
|---|---|---|---|
| PBM | $5.40 ($5.00–$7.00) | $11.40 ($10.00–$15.00) | $25.00 ($25.00) |
| HMO | $6.40 ($5.00–$10.00) | $15.40 ($10.00–$25.00) | $32.22 ($15.00–$40.00) |
| Total | $6.15 ($5.00–$10.00) | $14.40 ($10.00–$25.00) | $26.43 ($15.00–$40.00) |

Table 15–6 Financial Impact of Influence on Patient Behavior with Copayments

| *Formulary/ Copayment Tier* | *Net Prescription Cost* | *Copayment Amount* | *Net Cost to HMO* | *Net Cost to HMO by Use of Drug One Tier Lower* |
|---|---|---|---|---|
| Tier I (generic) | $15 | $5 | $10 | — |
| Tier II $50 preferred brand | $50 | $15 | $35 | $10 ($25 savings if Tier I drug is used) |
| Tier III $70 nonpreferred brand | $70 | $25 | $45 (if the Tier III product is used) If the Tier III, nonpreferred brand is used, the patient pays $25 copayment, and the HMO has a net exposure of $45 for this $70 product. | $35 ($10 savings if Tier II is used) However, if the patient is influenced because of the high $25 Tier III copayment to accept the Tier II product, the plan "saves" an additional $10 in the net cost of the Tier II product |

if the patient informs the physician on a subsequent visit of his or her concern over the copayment level that a physician would become aware of the copayment (or if a pharmacist contacts the physician on a patient's behalf).

However, by the time the patient has revisited the physician, the drug has likely been used for a month or two, and if effective, the patient will likely continue the medication. Medicare members may be an exception. They may be more likely to express concern over high copayment costs if their out-of-pocket expenses introduce a personal hardship or result in personal drug rationing.

Theoretically, in situations in which physicians are at financial risk for pharmacy benefits, there should be alignment of the financial interests of the patient and physician. That is, lower AWP products (preferred by physicians at financial risk) should also be preferred by patients because such products are likely to be in lower copayment tiers.[70]

However, there is a relative inelasticity of demand in this situation because physicians are not often aware of AWP drug prices and generally try to use the most effective product, despite the copayment tier. This is not universal, and some physicians are quite aware of AWP levels and may preferentially use less-expensive products whenever possible.

A confounding element is DTC advertising.[71] Patients may request higher AWP products on the basis of DTC advertising, and the physician may be unable to dissuade the patient without an extensive and time-consuming discussion. It is estimated that when a patient requests a DTC-advertised product, 40 percent of physicians simply prescribe the product without argument, and 40 percent of physicians attempt to convince the patients a less-expensive product is preferable. The introduction of higher copayments for nonpreferred drugs may assist the physician in dissuading the patient from using the DTC-advertised product. However, this is highly variable. One New York area health plan introduced a higher $50.00 prescription copayment on a nonpreferred, nonsedating antihistamine and experienced almost no change in patient use, presumably because of the impact of effective DTC advertising.

### Relationship of Copayments to Formulary Positioning

Increasingly, there is a contractual relationship between the formulary positioning of a drug product and the copayment associated with its use. MCOs and PBMs are using copayments to influence patient drug selection and utilization to increase the market share of contracted products. Contracts may also limit the number of drugs at specific copayment tiers. For example, a rebate contract may allow only two products to be "preferred" in the formulary and available at the second tier copayment. Additional brand products must be positioned in the formulary as "nonpreferred" and available only at the higher, third-tier copayment. Generic products within the category are available at the lowest (first tier) copayment (even though they may be preferred, generics do not violate the rebate contract requirements). This is illustrated in the Table 15–7.

A fourth copayment tier is being introduced for nonformulary products (for plans that do not use NDC blocks) or for noncovered, "lifestyle," or cosmetic drug products (i.e., for alopecia or male impotence). Fourth copayment tiers are frequently percent copayments (coinsurance), such as 50 percent up to a maximum dollar amount. Exhibit 15–1 illustrates how a drug formulary might be constructed to reflect drug copayment.

The net result is to allow access to more drugs previously not covered but require the patient who selects them to use these products in the third or fourth tier and to accept the financial responsibility for their decision. Health plans do not consider this an unfair penalty because they consider these third or fourth tier products (especially fourth tier products) to be optional and nonessential drugs for which there are formulary alternatives.

### Drug Utilization Review[72]

DUR is a common clinical pharmacy procedure that involves the thorough review of patient drug history records by a pharmacist to determine whether patient's drug use or physician's drug prescribing require intervention. Typically, the patient drug history is reviewed for unnecessary or redundant drug use, drug interactions, adverse effects, noncompliance, and lack of persistence.

DUR is a well-accepted quality assurance and improvement activity and is now mandated by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), NCQA, and the federal government (accreditation agencies are discussed in Chapter 26). The purpose of this activity is to ensure appropriate drug therapy. In 1972, Brodie published an important paper that defined the DUR process as the "ongoing study of the frequency of use and cost of drugs, from which patterns of prescribing, dispensing, and patient use can be determined."[73] An effective DUR program must have the authority to review the use of drugs through available information and to compare the observed use to standards identified by knowledgeable professionals.

Stolar furthered the concept of DUR by stating that for a DUR program to ensure the quality of drug use, it must be continuous, authorized, and structured. DUR programs must measure the use of drugs against predetermined criteria and initiate changes in drug use that do not meet these criteria.[74] The added criteria of continuous

Table 15–7 Relationship of Contract and Copayment Tier

| *Drug Product* | *Formulary Position* | *Copayment Tier* | *Copayment Example* |
|---|---|---|---|
| Generic | Preferred | First | $6.00 |
| Contracted brand | Preferred | Second | $12.00 |
| Noncontracted brand | Nonpreferred | Third | $25.00 |

review and intervention transformed DUR from simply a passive study of drug use patterns to an active evaluation and intervention program with defined outcomes.

DUR programs are qualitative studies with corrective action, prescriber feedback, and reevaluation. This not only achieves the improved patient care objective but also provides substantial educational benefit to the pharmacist and prescriber. By definition, "retrospective" review is conducted using historical records. However, a retrospective review generally is not timely enough to prevent acute drug use problems. Concurrent review processes are often established to address this problem area and are done by use of online, real-time, POS computer systems. The in-pharmacy POS computer system interacts with patient drug history maintained by the health plan or PBM. The system provides immediate clinical messages that may alert the pharmacist to drug use problems. Regardless of the source of the drug use records, a pharmacist is required to assess information and make contact with the patient's physicians to investigate or correct dangerous drug use patterns.

### Application of DUR in Pharmacy Benefit Management

Similar to formularies, DUR is a clinical pharmacy quantitative review process that began in hospitals and migrated to the outpatient, managed care environment because of the need to maximize outcomes and minimize costs. Managed care lends itself quite well to the DUR philosophy because managed care generally is associated with large amounts of data. DUR in managed care is conducted on a population basis, but interventions occur on a patient-specific basis. Hospitals and health care systems will use DUR concepts for accreditation purposes. As noted earlier, the Joint Commission incorporates DUR in its accreditation of hospitals, and the NCQA uses DUR concepts for its health plan accreditation and HEDIS measurements. Effective DUR counseling has been required for all Medicaid patients as of 1993, secondary to the Omnibus Budget Reconciliation Act of 1990. This act provides legislation for federal financial participation (FFP) payment for covered outpatient drugs under the Medicaid program. DUR programs have taken on many different appearances in managed care, but the common theme among all the programs is that they are designed to review physician prescribing, pharmacist dispensing, and patient use of medications in an attempt to minimize treatment variations and optimize patient care outcomes.[75]

## ROLE OF PHARMACY PROGRAMS IN DISEASE MANAGEMENT AND QUALITY IMPROVEMENT PROGRAMS

Disease management (DM) programs are integrated patient management activities with the goal of achieving the most cost-effective patient treatment outcomes. The DM programs attempt to improve clinical, economic, and quality-of-life outcomes. Such programs are possible in MCOs that have the ability to collect and merge medical claims and clinical data with pharmacy claims and establish effective management programs to achieve the desired outcomes. DM is discussed in Chapter 14 in greater depth but will be related to the pharmacy program administration here.

DM has been defined in various ways but is often considered to be a patient-focused, comprehensive approach to minimize the treatment variability of a specific disease to improve patient care outcomes and optimize the expenditure of resources.[76] DM programs fit well with pharmacy benefit management because DM concepts will help focus on the value of pharmaceuticals in their role in achieving clinical, economic, and quality-of-life outcomes. DM helps to shift the focus from the cost of drugs to the value of the pharmacy benefit program because DM broadens the focus to direct and indirect economic outcomes rather than only pharmacy component cost management.

This interest in qualitative outcomes was supported by the growth of organizations' quality improvement initiatives in health care, such as the NCQA and other similar quality improve-

ment entities. Payers, health care plans, and vendors saw DM as a tool to implement quality improvement strategies into the delivery of health care services. Because health care is a market-driven business, health plans also saw their ability to document the quality of care provided by their physicians and hospitals as an important marketing tool to grow their membership and reduce enrollee turnover.

DM is a continuous, coordinated evolutionary process that seeks to manage and improve the health status of the affected patient subpopulation over the entire course of the disease.[77] When clinical guidelines deal with the treatment of a disease, DM, or health management, is a comprehensive program that deals with each aspect of health care along the continuum of an identified disease, from detection to treatment to follow-up. Those diseases that are chosen are often chronic diseases in which there is evidence that associated care processes bring about measurable improvements in the patient's health status. Diseases are also targeted that consume a large amount of resources or are associated with a high overall cost. Examples of diseases treated by DM programs include asthma, diabetes, hypercholesterolemia, hypertension, congestive heart failure, diabetes, depression, AIDS, cancer, and osteoporosis. The formulary and clinical guidelines are also involved because the formulary provides the most cost-effective drugs available, and guidelines help ensure they are used appropriately. DM programs can lead to positive economic outcomes that identify those drugs that, when appropriately used, effectively minimize costs and maximize outcomes associated with specific, targeted medical conditions.

## QUALITY IMPROVEMENT IN PHARMACY BENEFIT MANAGEMENT[78]

The NCQA established HEDIS as the first organized set of performance measures to evaluate the quality of managed care plans. Specific HEDIS measures are associated with accurate and appropriate delivery of the pharmacy benefit. Often the health plan will "carve out" the pharmacy benefits to a PBM. As an outside vendor of the health plan's services, the PBM is responsible to the health plan for collecting the pharmacy data needed to report these specific HEDIS measures. These data must then be matched with the health plan's medical claims data because all information for one patient can be scattered across several different databases.

Integrating medical and pharmacy claims data is a challenging process that is necessary to meet HEDIS and NCQA accreditation requirements.[79] Medical conditions and diseases are most often coded by the International Code for Diagnoses (ICD-9 or ICD-10), whereas procedures are coded by the American Medical Association's Physicians' Current Procedural Terminology (CPT). Codes for pharmaceuticals have not been yet standardized into one internationally recognized code. Generic product identifier (GPI) and generic code name (GCN) are just two examples of nationally recognized index codes for pharmaceuticals owned by FirstDataBank, a pharmacy data and information management company. Most of the HEDIS measures do not involve pharmaceuticals, although this is rapidly changing. Some of the current measures that involve pharmacy benefits include those found in Table 15–8. The reader is referred to Chapter 20, and specifically Figures 35–1 and 35–2, for the complete HEDIS measures.

## MEASURING PHARMACY BENEFIT MANAGEMENT PROGRAM PERFORMANCE

The competitive managed care environment requires that health plan and PBM pharmacy programs are successful from a clinical, patient satisfaction, and economic perspective. The pharmacy program manager will monitor specific performance metrics on a monthly basis (see following) and attempt to modify controllable factors if performance measures suggest costs are rising more than forecast, member satisfaction is declining, drug-related clinical outcomes are being achieved, or other markers of poor pharmacy program performance are indicated.

Table 15–8 Examples of HEDIS Measures Requiring Pharmacy Data

| *Domain* | *Measure* | *Description* | *Pharmacy Data to Report* |
|---|---|---|---|
| Effectiveness of care | Beta-blocker treatment after a heart attack | % members 35 years who were hospitalized and discharged with a diagnosis of AMI and who received a Rx for β-blockers on discharge | Members who received an outpatient Rx within 30 days before admission for AMI to 7 days after discharge |
| | Eye examinations for people with diabetes | % members 31 years with type I or II diabetes who had a retinal examination within the year | Identification of population: those members dispensed insulin, oral hypoglycemics, antihyperglycemics |
| | Comprehensive diabetes care | % of members 18–75 years with type I or II diabetes who had HbA1c, lipids, eyes, and kidneys monitored during the year | Identification of population: those members dispensed insulin, oral hypoglycemics, antihyperglycemics |
| | Antidepressant medication management | % members 18 years diagnosed with a new episode of depression, treated with medication: acute and continuation phase follow-up | Members diagnosed with a new episode of major depressive disorder treated with antidepressant meds |
| Use of services | Outpatient drug utilization | Summary of drug use: average # and cost of Rx's PMPM, total # and cost of Rx's; stratified by age and payer | "Prescription" is defined as one 30-day (or less) supply of pharmaceuticals *or* one supply requiring a copay |

AMI = acute myocardial infarction; Rx = prescription

*Source:* Adapted from Amelia Goodwin, Quality Improvement Initiatives in Managed Care, in *Managed Care Pharmacy Practice*, R.P. Navarro, ed., p. 300, © 1999, Aspen Publishers, Inc. Copayment information added by Robert P. Navarro, 2000.

An MCO tries to accomplish the following objectives to achieve the cost, access, and quality of care goals:

- implement and maintain a comprehensive, cost-effective, and dynamic drug formulary program, including an exception or PA process, to meet all reasonable patient care needs as defined in the certificate of coverage
- develop a responsible pharmacy program member service function to ensure members access pharmacy benefits most effectively
- construct a pharmacy provider network to include a participating pharmacy within a reasonable distance of member homes and offices (usually 1 to 5 miles)
- develop drug utilization review and other quality improvement programs to help optimize drug performance and provide intervention for patients requiring special assistance in achieving pharmacy program outcomes

The pharmacy program must also meet strict budgetary and performance objectives. The basic performance benchmarks monitored usually include the following measurements:

- total prescription program costs (dollars)

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- monthly (PMPM) and annual (PMPY) program costs
- prescription utilization (PMPM and PMPY). The PMPY utilization rate for HMOs with managed pharmacy programs is now in the 7 to 9 prescriptions PMPY range for a non-Medicare population.[80]
- administrative and claims processing fees (per prescription and per patient)
- prescription discount or rebate (total amount, per prescription, and per patient)
- generic dispensing rate (overall, by pharmacy, by therapeutic class, and by physician)
- drug formulary conformance rate (overall, by physician, and by pharmacy)
- patient satisfaction and member complaints related to the pharmacy program
- number of drug formulary exception requests and approvals
- trend of all the preceding performance measurements measured monthly, quarterly, and annually

There are many more performance measurements pharmacy directors routinely monitor, especially with more sophisticated programs that may include drug formulary conversion, compliance, and persistence activities. However, with the preceding basic performance measurements, a pharmacy director can evaluate the effectiveness of his or her prescription drug management program.

### Budgeting and Planning To Achieve Pharmacy Program Performance Goals

Pharmacy program performance goals can only be achieved with a well-designed and executed pharmacy program plan. By the late summer or early fall, the pharmacy program manager is told the membership, marketing, financial, benefit design, and other plan characteristics that will influence the cost and use of pharmaceuticals in the subsequent year, as well as his or her budget, to achieve specific PMPM and PMPY cost goals. The pharmacy manager must then allocate financial and human resources to appropriate tasks to achieve the forecast budget goals. Because most employer groups renew their contract in January, and the contract is generally in force for 12 months, the pharmacy manager has limitations on what benefit design or copayment changes can be made throughout the year to compensate for higher-than-budget pharmacy cost experience. Therefore, accurate budgeting and planning must occur before the benefit design or premium and copayment levels are established because they often cannot be changed for 12 months.

When a new drug is launched, the pharmacy manager attempts to determine the cost (if not known before launch) and the potential utilization because it is the product of these factors that will determine the total forecast cost impact of the new drug. Hedayati and Kleinstiver propose a novel cost impact model.[81]

## FUTURE CHANGES IN PHARMACY BENEFIT MANAGEMENT

The evolution of pharmacy benefit management depends heavily on technological advances, first in the arena of biotechnology, high throughput, combinatorial chemistry that will deliver more effective and efficient but more expensive pharmaceuticals, and the second in the area of information processing and communications.

High throughput and combinatorial chemistry will allow a geometric improvement in the number of chemicals that can be analyzed for potential human value and will allow chemists to develop patient-specific drug therapy that will virtually ensure therapeutic outcomes. The price for these compounds will likely be high, and economic and ethical arguments will occur regarding the patient's, health plan's, and employer group's willingness to pay for such outcomes. The role of health economics will become more important as esoteric concepts such as quality of life and functional status are

incorporated into formulary and benefit design coverage decisions.

The information storage and processing advances will allow the ability to identify patient candidates for intervention, monitor outcomes, and conduct population-based outcomes research to refine drug therapy, formulary decisions, and treatment guidelines. Information warehouses will also support economic research regarding the coverage issues of expensive biotechnology products, discussed previously. Advances in communications will provide patient-specific clinical data to the physician at the point of prescribing to maximize outcomes and minimize adverse drug events. The Internet will advance patient access to health and drug information, provide patient-specific monitoring and educational opportunities, allow Internet access to drug distribution channels, and in general increase the health knowledge status of patients. This will likely result in greater individual responsibility for health care outcomes and allow the patient to make better informed decisions on how to spend his or her health care premium and copayment dollars.

## CONCLUSION

Prescription drugs are a highly used and aggressively managed health benefit offered by managed care. Purchasers of pharmacy benefits continue to focus on drug costs, especially because of the double-digit pharmacy program annual trend rate of the past few years for many payers. Pharmacy program managers must focus on the value that appropriately used pharmaceuticals can have on total direct economic, clinical, and quality of life outcomes.

### *Study Questions*

1. How have the pharmacy program costs and trends compared with physician and hospital component costs over the last 15 years?
2. What are the essential elements of a managed care pharmacy benefit management program?
3. What are the components of pharmacy program costs?
4. What are the basic metrics used to measure the performance of a pharmacy benefit management program?
5. What are the advantages and disadvantages for an HMO in using a PBM to manage its pharmacy services?
6. How are pharmacoeconomic data used in the drug formulary decision process?
7. What is the impact of prescription co-payments on pharmacy program costs, drug access, and utilization?
8. What has been the impact of NCQA HEDIS measures and disease management on pharmacy programs?

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